APR 12 2012

Section 11. 510(k) Summary

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: ___k113768_____

1. Submitter's Identification:
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   Correspondent:
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   Prepared date: December 19, 2011

2. Device name:
   Proprietary name: U-RIGHT TD-4280 Blood Glucose Monitoring System

   Regulatory information:
   A. Regulation section: 21 CFR 862.1345 Glucose Test System
   B. Classification: Class II
   C. Product Code: LFR, Glucose Dehydrogenase, Glucose
      NBW, System, Test, Blood Glucose, Over the Counter
   D. Panel: Clinical Chemistry (75)

3. Intended Use:

   The U-RIGHT TD-4280 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples from the finger. It is intended to be used by a single person and should not be shared.

   The U-RIGHT TD-4280 Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus or be used on neonates. The meter contains speaking functions but is not intended for use by visually impaired users.

   The U-RIGHT TD-4280 Blood Glucose Test Strips are for use with the U-RIGHT TD-4280 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples.

4. Device Description:

   The system consists of three main products: the meter, test strips, and control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results.

5. Substantial Equivalence Information:

   A. Predicate device name: TD-4277 Blood Glucose Monitoring System
   B. Predicate K number: K100322
   C. Comparison with predicate:

   The modified U-RIGHT TD-4280 Blood Glucose Monitoring System has the following similarities to the predicate device:

   - same operating principle,
   - same fundamental scientific technology,
   - incorporate the same basic circuit design,
   - incorporate the same materials,
   - same shelf life
   - packaged using the same materials, and
   - manufactured by the same process.

The modifications encompass:

- Addition of the speaking function
- Modification in the physical appearance
- Minor software modifications of the glucose meter
- Change of the data transmission method from USB to RS-232
- Reduced the memory capacity from 1000 measurement to 450 measurement
- Labeling change due to the above modifications

6. Test Principle:
   The detection and measurement of glucose in blood is by an electrochemical biosensor technology using glucose dehydrogenase.

7. Performance Characteristics:
   U-RIGHT TD-4280 Blood Glucose Monitoring System has the same performance characteristics as the predicate device.

   A comparison of system accuracy performance demonstrated that the U-RIGHT TD-4280 Blood Glucose Monitoring System and the TD-4277 Blood Glucose Monitoring System are substantially equivalent.

   Software verification and validation testing confirmed that the performance, safety and effectiveness of the U-RIGHT TD-4280 Blood Glucose Monitoring System are equivalent to the predicate device.

8. Conclusion:
   Based on the information provided in this submission, the U-RIGHT TD-4280 Blood Glucose Monitoring System is substantially equivalent to the predicate TD-4277 Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

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APR 12 2012

Re: k113768
Trade Name: U-Right TD-4280 Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, LFR
Dated: March 12, 2012
Received: March 15, 2012

Dear Meiru Li

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Attachment E.

Indications for Use

510(k) Number (if known):

Device Name: U-RIGHT TD-4280 Blood Glucose Monitoring System, model TD-4280

Indications for Use:

The U-RIGHT TD-4280 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples from the finger. It is intended to be used by a single person and should not be shared.

The U-RIGHT TD-4280 Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus or be used on neonates. The meter contains speaking functions but is not intended for use by visually impaired users.

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Prescription Use ____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K113768